Message Text

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TO AMEMBASSY LISBON

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E.O. 11652: N/A
TAGS: EIND, TBIO, PO
SUBJECT: FDA REJECTION OF PORTUGUESE PIGNOLIA NUTS

REFERENCE: LISBON 1060

1. FDA HAS REVIEWED ITS FILES ON THIS MATTER. FACTS ARE
AS FOLLOWS AND RESPONSE IS KEYED TO EACH ITEM OF REFTEL.

-ON 12/3/74 NEW YORK DISTRICT DETAINED 800 CARTONS OF SHELLED
PIGNOLIA NUTS DUE TO THE FINDING OF ESCHERICHIA COLI IN FDA
SAMPLE 031894. (E. COLI IS A MICROORGANISM OF FECAL ORIGIN -
ISOLATION INDICATES PRODUCT IS CONTAMINATED WITH FILTH).
WITH FDA PERMISSION, STEVE REGGIO CO., INC., N.Y. - AGENT FOR
THE FOREIGN SHIPPER - HAD SAMPLE DRAWN FROM THE 800 CTN. LOT
WHICH WAS ANALYZED BY FITELSON LABS., INS., N.Y. AND FOUND
NEGATIVE FOR E. COLI. HOWEVER, FITELSON LABS DID NOT ANALYZE
IN ACCORD WITH ACCEPTABLE PROCEDURES - THEY COMPOSITED 25
SUBSAMPLES INTO 5 AND ANALYZED ONLY 5. FDA METHOD REQUIRES
INDIVIDUAL SUB ANALYSIS. FDA HAS REVIEWED ANALYTICAL RESULTS
ON ITS SAMPLE 031894 AND INSPECTOR'S SAMPLING TECHNIQUE AND
FOUND NO DISCREPANCIES FROM PRESCRIBED PROCEDURES UPON WHICH
TO RE-EXAMINE. CONTAMINATION MAY NOT BE UNIFORMLY DISTRIBUTED
THROUGHOUT LOT, THEREFORE, NEGATIVE FINDINGS BY A COMMERCIAL
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LAB WOULD NOT INVALIDATE FDA RESULTS.

-FDA DOES NOT FEEL THE 800 CARTON LOT SHOULD ARBIRARILY BE SUBDIVIDED INTO 4 LOTS FOR SHIPPER'S CONVENIENCE. THIS WOULD VIOLATE FDA POLICY FOR SAMPLING GOODS OFFERED FOR IMPORT. THERE IS NO INTENT OR PRACTICE OF DISCRIMINATION AGAINST GOODS FROM PORTUGAL OR ANY OTHER COUNTRY.

-FDA HAS DETAINED, NOT RPT NOT REJECTED LOT. HAS NOT APPROVED PROPOSED RECONDITIONING PROCEDURE. FDA ACTION NOT INFLUENCED IN ANY MANNER BY IMPORTERS OR MARKET PRICE. FDA CONCERNED SOLELY WITH SAFETY, SANITARY QUALITY, AND WHOLESOMENESS OF GOODS.

-FDA HAS ADVISED IMPORTER OF RECORD, THE CONSIGNEE, AND AGENT FOR FOREIGN SHIPPER THAT IT WILL NOT RE-SAMPLE LOT, BUT WOULD CONSIDER APPLICATION FOR AUTHORIZATION TO RECONDITION. IN RESPONSE, CONSIGNEE, FULD BAKERS SUPPLY, PROPOSED TO RECONDITION BY USE OF PROPYLENE OXIDE. REQUEST DENIED ON BASIS THAT METHOD WAS NOT A SUITABLE MEANS OF REMOVING FECAL FILTH. PROPYLENE OXIDE IS A GASEOUS STERILANT - USE ON SUBJECT PRODUCT WOULD RESULT IN STERILZED FILTH.

-GOODS ARE CURRENTLY UNDER DETENTION AND FDA STILL WILLING TO CONSIDER APPLICATION FOR PROPER RE-CONDITIONING. AGENT FOR SHIPPER IS AWARE OF AN ACCEPTABLE PROCEDURE (WASH WITH CHOLORINE SOLUTION, FOLLOWED BY DRYING).

-.FDA INTENDS TO KEEP FILE OPEN FOR ANOTHER 2 OR 3 WEEKS TO ALLOW IMPORTER OF RECORD, HUDSON SHIPPING CO., TO PROPOSE SUITABLE METHOD OF RE-CONDITIONING THE LOT. IF IMPORTER DOES NOT AVAIL HIMSELF OF THIS OPPORTUNITY, FDA WILL HAVE NO ALTERNATIVE BUT TO REFUSE ENTRY TO THE GOODS, AND CLOSE THE FILE. INGERSOLL

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